EXPERT PANEL REVIEW

OF THE COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS

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1.0 BACKGROUND

The E. coli O157:H7 spinach outbreak in 2006 led to an industrywide initiative led by Western Growers to develop food safety best practices for the production and harvest of leafy greens. This industry effort culminated in 2007 with the publication of the "Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens" (the Guidelines). That same year the California Leafy Greens Handler Marketing Agreement (CALGMA) was formed under the oversight of the California Department of Food and Agriculture (CDFA), which established a mandatory audit program to verify that all growers selling to handlers that are signatories of the marketing agreement, produce and harvest lettuce and leafy greens in accordance with the Guidelines. Western Growers, a leading specialty crop industry association, manages the Guidelines and facilitates a change control process for the industry to submit new practices or to revise existing practices based on new research findings and/or operational improvements. Proposed revisions are reviewed and accepted/rejected by the CALGMA Technical Committee that then makes recommendations to the Advisory Board, which has the authority to approve revisions.

CALGMA members use these Guidelines to design and implement food safety programs. While the Guidelines are specifically focused on improving lettuce and leafy greens in-field production and harvest food safety operations, many companies now use them for all crops they grow and harvest.

The Guidelines identify and address:

- Food safety best practices for leafy greens based on the current scientific research findings;
- Practical food safety measures and procedures for lettuce/leafy greens growers and handlers to follow;
- Key food safety risks in five areas – water use, soil amendments, general requirements, worker practices / field operations, and environmental assessments such as adjacent and historical land use, animal intrusion, and flooding.

Since their initial release, the Guidelines have been updated 12 times. The current version was published on August 2, 2013. Accepted revisions include clarifications as well as improvements in food safety practices. In addition, in 2011, Congress approved and the President signed into law the new Food Safety Modernization Act which will mandate "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption", commonly referred to as the "Produce Rule". The Produce Rule will require producers of raw agricultural commodities that are not normally cooked prior to consumption including leafy green producers to develop and implement food safety programs in their operations. With the many changes in the specialty crop industry, the CALGMA asked Western Growers to facilitate an outside, independent expert review of the current Guidelines to ensure the CALGMA remains a strong preventive program that minimizes the risk of microbial contamination in fresh produce production and harvest operations.

2.0 EXPERT REVIEW

Between July and September 2015, Western Growers convened a group of food safety experts to evaluate the current edition of the Guidelines and assess whether the Guidelines improve lettuce and leafy greens food safety by reducing the risk of human pathogen contamination during in-field production and harvest.

The review panel was comprised of four leading experts chosen for their research and work- related experience in the field of fresh produce food safety – Dr. Robert E. Brackett, Dr. Michele Jay-Russell, Dr. Kali E. Kniel, and Dr. Manan Sharma. Other factors that were considered in choosing reviewers were geographical and institutional diversity.

Robert E. Brackett, Ph.D., is Vice President and Director of the Institute for Food Safety and Health (IFSH) at the Illinois Institute of Technology. Prior to his current positions at IFSH, Dr. Brackett held positions at the Grocery Manufacturing Association and the U.S. Food and Drug Administration. Dr. Brackett's research interests include microbiological food safety, growth and survival of psychrotrophic pathogens in foods, physical and chemical controls for pathogens in foods, and microbial ecology of plant products.

Michele Jay-Russell, Ph.D., D.V.M., M.P.V.M., is Project Director of the Western Center for Food Safety at University of California, Davis. Dr. Jay-Russell was a contributor to the first edition of the Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain published in 2006. Her research interests are in food safety and veterinary public health with an emphasis on the molecular epidemiology of zoonotic enteric pathogens. In her outreach and educational work as a food safety specialist, Dr. Jay-Russell works with stakeholders to protect specialty crops from microbial contamination using methods that also promote environmental stewardship on the farm.

Kali E. Kniel, Ph.D., is a professor of microbial food safety at the University of Delaware. Her research focuses on food and waterborne protozoa and viruses and use of non-thermal methods to inactivate these organisms on fresh produce. She has conducted field research on removing human pathogens from irrigation water used on fresh produce crops. Prior to her position at the University of Delaware, Dr. Kniel was a microbiologist with the USDA Agricultural Research Service.

Manan Sharma, Ph.D., is a research microbiologist in the Environmental and Microbial Food Safety Laboratory with the Agricultural Research Service at the U.S. Department of Agriculture. Dr. Sharma's research focuses on the survival, persistence and growth of Escherichia coli O157:H7 in leafy green pre-harvest environments i.e., soil and water, and the examination of various potential intervention strategies.

For the review, the experts were given the following resources:

- The latest version (August 2, 2013) of the Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens, and
- A comparison of the best practices in the Guidelines to the provisions of the proposed FSMA rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Rule), prepared by iDecisionSciences, LLC.

The experts were asked to summarize the results of their review and using their professional judgment answer the following three questions:

1. Do the practices in the current edition of the Guidelines represent the most current microbial food safety best practices for the production and harvest of lettuce and leafy greens?

2. Do the CALGMA's accepted food safety practices (the Guidelines) provide the same level of public health protection as the applicable requirements proposed in the Produce Rule?

3. Has the implementation of these guidelines in California and Arizona, coupled with the California Department of Food and Agriculture (CDFA) audit program reduced the risk of human pathogen contamination in lettuce and leafy green crops?

2.1 *Do the practices in the current edition of the CALGMA's accepted food safety practices (the Guidelines) represent the most current microbial food safety best practices for the production and harvest of lettuce and leafy greens?*

Overall the expert reviewers agreed that the current edition of the Guidelines represent the most current microbial food safety practices for the production and harvest of lettuce and leafy greens. Dr. Brackett summarized his view on the relevancy of the Guidelines when he said:

"It is my opinion after a careful reading (of) the most recent draft of the Guidelines that the recommendations contained within the Guidelines do represent the most current microbial food safety best practices at this point in time and with existing technology."

Commenting specifically on the best practices for irrigation water, Dr. Kniel affirmed the validity of the information currently provided in the Guidelines for water testing including testing frequency and exemptions in the absence of more concrete data. However, reviewers addressed several areas they believed forthcoming peer-reviewed published research will eventually support changes to the Guidelines' best practices including irrigation water testing, uncomposted soil amendments, soil amendment testing method, and replanting waiting period following flooding.

Although Dr. Manan Sharma stated that in most cases he believed the Guidelines represented the most current microbial food safety best practices, he also pointed out several areas where he believed there is recently published research that may support a modification to soil amendment best practices including: 1) the distance separating leafy green growing operations and CAFOs/composting operations (Berry, 2014; Callahan, 2015), 2) use of the U.S. Environmental Protection Agency's methods (EPA method 1680) for fecal coliform testing, which Reynnells et al. (2014) demonstrated to be more sensitive in recovering E. coli from finished compost than the U.S. Composting Council Test Methods for Examination of Compost and Composting (USCC TMECC 7.01) methods for fecal coliforms, and 3) the addition of non- O157 Shiga toxin-producing E. coli and Listeria monocytogenes to target organisms for compost testing.

2.2 *Do the Guidelines provide the same level of public health protection as the applicable requirements proposed in the Produce Rule?*

All four reviewers stated that they believed the Guidelines provided the same level of public health protection as the applicable requirements proposed in the Produce Rule (including the supplemental notice). Moreover, all four reviewers stated that they believed the Guidelines likely resulted in greater public health protection by including detailed criteria and instructions specifically for the following areas – sampling procedures and test methods for water testing and soil amendments. Dr. Jay-Russell wrote about the significant differences in the level of detail contained in the two documents and expressed her belief that these extra details included in the Guidelines "should complement and strengthen food safety efforts related to leafy greens through the [Produce] Rule." Dr. Sharma specifically called out the Guidelines' requirements for uncomposted soil amendments and microbial criteria for irrigation water that has contact with plants as "more stringent" than the Produce Rule.

In her report, Dr. Kniel identified three steps that are critical for food safety guidelines to achieve public health protection: adoption, implementation and utilization, and warns that ambiguity impedes these actions by not working "towards protection of the greater good for public health." She asserts that the Guidelines are successful in these three areas due to the use of "understandable and applicable language" and "descriptive phrases…that describe to growers exactly how some risks may occur." She further states:

"…the written language is especially critical to utilization. If a document is going to be utilized it must be clear. The [CA]LGMA includes terms already familiar to many growers, like SOPs and reflection back to GAPs, on which some growers have been trained for >15 years."

In particular she mentions the use of decision trees and microbiological explanations using language that industry can easily understand as helpful resources for Guideline users.

2.3 *Has the implementation of these guidelines in California and Arizona, coupled with the California Department of Food and Agriculture (CDFA) audit program reduced the risk of human pathogen contamination in lettuce and leafy green crops?*

All the reviewers expressed confidence that the Guidelines have likely contributed to reducing the human pathogen contamination risk in leafy greens although some struggled with finding supportive data to prove their general positive sense of a decreased risk. Dr. Brackett states

that his "common sense" opinion is that implementation of the Guidelines in California and Arizona likely reduced the human pathogen contamination risk. Along with providing her affirmative opinion regarding the Guidelines' positive effect on contamination reduction, Dr. Jay-Russell acknowledged the difficulty in definitively quantifying that reduction in her comments:

"…one of the major challenges in trying to evaluate disease prevention programs is the inability to 'prove a negative.' In other words, it is not possible to absolutely quantify the number of illnesses or outbreaks that were eliminated or reduced through prevention activities."

Reviewers also cited passive existing U.S. surveillance and reporting systems and lack of outbreak investigation standards among state public health departments as limitations in assessing the Guidelines' effect on foodborne illness with certainty.

Dr. Kniel testified that the Guidelines and the CALGMA program successfully established a culture of food safety on leafy green farms that is essential for reducing pathogen contamination risk and creating a behavior-based food safety system as described by Frank Yiannis (2010) in his book, Food Safety Culture. Dr. Jay-Russell cited the lack of a large multi- state outbreak comparable to the 2006 spinach E. coli O157:H7 outbreak as suggesting that the Guidelines have likely contributed to reduced human pathogen contamination in leafy greens.

2.4 *Other comments*

Dr. Jay-Russell commended the CALGMA program for its flexibility in routinely incorporating new research findings into the Guideline's best practices. She included in her praise of the dynamic nature of the Guidelines, the CALGMA's leadership and staff's communication of best practice revisions to members through workshops and trainings as well as prominent documentation of changes on the front page of the Guidelines.

3.0 SUMMARY AND CONCLUSIONS

This review was catalyzed by the multiple updates the Guidelines have undergone based on improved practices in the industry and new research findings since the previous expert review. After studying the current guidelines as well as a matrix that compared provisions of the proposed Produce Rule (including the supplemental notice modifications), reviewers were overwhelmingly supportive of the CALGMA program specifically attributing the success of the program to the Guidelines' accepted food safety practices. All the reviewers affirmed that the Guidelines provide at least the same level of public health protection as the applicable requirements in the Produce Rule with some reviewers citing areas where they believed the Guidelines provided more detailed guidance and were consequently more rigorous than the rule. They expressed confidence that the program will remain effective in light of the organized process used to incorporate new research findings and improved best practices. Dr. Jay-Russell asserts that the greatest strength of the CALGMA program is "the timely engagement of multi- disciplinary experts and extensive review of the scientific literature used to develop and update the Guidelines." To maintain the strength of the CALGMA program, it is recommended that Western Growers work with the CALGMA to address the specific proposed modifications to the Guidelines put forward by the experts.

4.0 REFERENCES

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